



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: “Griffithsin compositions for treatment and prevention of anti-viral infections”

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to University of Louisville Research Foundation, (“ULRF”) in its rights to the inventions and patents listed in the Supplementary Information section of this notice. ULRF is a Kentucky 501(c)3 non-profit corporation that is the agent of the University of Louisville (“UofL”) for licensing intellectual property owned and controlled by ULRF on behalf of UofL.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Taryn Dick, Ph.D., MBA, Licensing and Patenting Manager at Telephone: (301) 631-3007 or E-mail: taryn.dick@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to ULRF: U.S. Provisional Patent Application No. 63/026,375 entitled “Compositions and Methods for Prevention of Coronavirus Infection,” (HHS Ref. No. E-029-2022-0-US-01), filed 18 May 2020; PCT Application

No. PCT/US2021/033009 entitled “Compositions and Methods for Prevention of Coronavirus Infection,” (HHS Ref. No. E-029-2022-1-PCT-02), filed May 18, 2021; U.S. Provisional Patent Application No. 62/898,383 entitled “Anti-Viral Compositions and Methods of Making and Using,” (HHS Ref. No. E-030-2022-0-US-01), filed September 10, 2019; and PCT Application No. PCT/US2020/050200, entitled “Anti-Viral Compositions and Methods of Making and Using” (HHS Ref. No. E-030-2022-0-PCT-02), filed September 10, 2020.

PCT/US2021/033009 described above claims priority to the U.S. Provisional Patent Application No. 63/026,375 described above, as well as a second U.S. Provisional Patent Application No. 63/070,375 entitled “Q-Griffithsin Nasal Spray,” (HHS Ref. No. E-029-2022-1-US-01), filed on August 26, 2020. The Government of the United States is not a co-owner on this second US Provisional Patent Application, and it is therefore, excluded from the proposed exclusive grant from NCI to ULRF.

With respect to the inventions described and claimed in the patent applications 62/026,375 (E-029-2022-0-US-01) and PCT/US2021/033009 (E- 029-2022-1-PCT-02) each of the inventors has assigned their rights to their respective employers or an entity which manages the intellectual property for their employer (The Government of the United States of America, the University of Louisville Research Foundation, Inc. or the University of Pittsburgh). With respect to the inventions described and claimed in the patent applications 62/898,383 (E-030-2022-0-US-01) and PCT/US2021/050200 (E-030-2022-0-PCT-01) each of the inventors has assigned their rights to their respective employers or an entity which manages the intellectual property for their employer (The Government of the United States or the University of Louisville Research Foundation, Inc.). The prospective patent license will be for the purpose of consolidating the patent rights to ULRF, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development

of the inventions, consistent with the goals of the Bayh-Dole Act codified as 35 USC §200-212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by ULRF will be subject to the provisions of 37 CFR Part 401 and 404.

Griffithsin (GRFT) is a protein that was originally isolated from marine red algae, namely Rhodophyte (*Griffithsia* sp.). It binds the terminal mannose residues of N-linked glycans found on the surface of many enveloped viruses such as HIV, SARS-CoV, Ebola virus, and more. The E-029-2022 invention pertains to novel mutant Griffithsin (GRFT) formulations and methods of inhibition of viral infection. The E-030-2022 invention pertains to methods of systemically treating viral infections and additional mutant GRFT variants that are specifically mutated to introduce a lysine within a mutant GRFT sequence. These GRFT variants can be PEGylated, which significantly improves pharmacokinetics and decreases immunogenicity. Based on current available data, the intended use for the inventions is as anti-viral therapies for enveloped virus infections.

This notice is made pursuant to 35 U.S.C. §209 and 37 CFR Part 404. The prospective exclusive patent license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. §209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C §552.

Dated: December 21, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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